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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,237	12/01/2003	Adrian Forster	FORSTER1	9763
1444 7590 02/22/2007 BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			EXAMINER STULII, VERA	
			ART UNIT 1761	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/22/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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**Office Action Summary**

Application No.

10/724,237

Applicant(s)

FORSTER ET AL.

Examiner

Vera Stulii

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112***

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the phrase "highly compressed CO<sub>2</sub> " renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Claim 1 also conflicts with claim 3. It is not clear if extraction recited in claim 1 is the same as recited in claim 3, since claim 1 recites "highly compressed CO<sub>2</sub> " and claim 3 does not.

#### ***Claim Rejections - 35 USC § 103***

**Claims 1-2 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhrts (US 2003/0228369) in view of Pilz et al (US 4,263,253).**

In regard to claim 1, 2 Kuhrts discloses supercritical carbon dioxide extraction [0043]. Kuhrts teaches that "CO<sub>2</sub> is the most commonly used material in supercritical fluid extraction and fractionation. Supercritical CO<sub>2</sub> extraction also allows for better separation and fractionation of certain components in hops" [0043]. Kuhrts also teaches that extraction of hops yields high concentration of alpha acids [0047] and one of the

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primary alpha-acids is xanthohumol. [0045]. In regard to claim 8, Kuhrts discloses producing powders from high viscosity fluids by mixing high viscosity fluid and absorbing agent (Abstract).

Kuhrts does not teach specific values of extraction parameters such as pressure and temperature.

Pilz et al teach dissolving a solid in a gas which is under supercritical conditions of temperature and pressure (Col. 2 lines 19-20). Pilz et al also disclose "[g]ases which are known to be capable, in the compressed and particularly in the supercritical condition, of even dissolving substances which are not easily volatilised are suitable for this purpose. When the pressure is lowered, this solvent capacity is very rapidly lost (frequently already in the region from 20 to 50 bars) and the solubility of the gas in the substance which is then precipitated also becomes so small with decreasing pressure that, when the pressure is lowered to atmospheric pressure, previously dissolved substances are recovered in very pure form" (Col.1 lines 48-58). Thus Pilz et al teaches that solvent capacity decreases with decrease in pressure. Pilz et al teach that solubility effect in compressed supercritical gases has been known for approximately 100 years (Col.1 lines 59-61). Pilz also teaches that "reference to "supercritical" conditions means under conditions which are above critical temperature and pressure and a "supercritical gas" is a gas under supercritical conditions" (Col. 2 lines 13-16). Pilz et al teach carbon dioxide as a supercritical solvent. Pilz et al teach that the process is carried out under pressures between 20 and 1200 bar (Col. 2 lines 52-53) and temperature range from

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20 to 140°C (Col. 2 lines 48-49). Pilz et al also teach the use of supercritical gases is particularly suitable for solids which required to be very pure (Col. 2 lines 27-28).

Since Kuhrts teaches extraction of hops with supercritical carbon dioxide and Pilz et al discloses specific parameters for supercritical carbon dioxide as a solvent, it would have been obvious to one of the ordinary skill in the art at the time the invention was made to modify the disclosure of Kuhrts et al and to apply temperature and pressure ranges taught by Pilz et al in order to produce a pure extract as disclosed by Pilz et al. As taught by Pilz et al, solvent has a better capacity when pressure is higher. One of ordinary skill in the art would have been motivated to increase pressure during supercritical CO<sub>2</sub> extraction in order to produce more concentrated extract.

#### ***Response to Arguments***

Applicant's arguments with respect to claims 1, 2 and 8 (p.8 of Reply to the Office Action of 07/26/2006) have been considered but are moot in view of the new ground(s) of rejection.

At page 8 of the response, applicant states that "Kuhrts does not refer to a method producing xanthohumol concentrated extract". This is not deemed persuasive, since Kuhrts teaches that extraction of hops with supercritical carbon dioxide yields high concentration of alpha acids [0047] and one of the primary alpha-acids is xanthohumol [0045].

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**Claims 3-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhrts (US 2003/0228369) in view of Pilz et al (US 4,263,253), Erdelmeier et al. (US 2005/0042318) and Babish et al. (US 2003/0113393).**

In regard to claims 3-7 Kuhrts et al. discloses use of hop pellets [0044] in supercritical CO<sub>2</sub> extraction.

Kuhrts et al. are silent about subsequent extractions with CO<sub>2</sub> under supercritical conditions. However, Erdelmeier et al. teach one or more extractions of a hop drug using supercritical CO<sub>2</sub> [0023], "preferably carried out once, twice or three times, particularly three times" [0028].

Kuhrts et al. are also silent about separation of xanthohumol-concentrated hop extract. However, Babish et al. teach a step of solvent removal after extraction [0014]. Babish et al. teach "the removal of CO<sub>2</sub>, however, simply involves a release of pressure to volatilize the CO<sub>2</sub>" [0014].

As evidenced by Erdelmeier et al., it was well known in the art to carry out several extractions of hop material using supercritical carbon dioxide in order to increase content of prenylated chalcones (xanthohumol). It would have been obvious to one skilled in the art to subject hop pellets to several subsequent extractions using supercritical carbon dioxide as a solvent in order to produce an extract with a high content of xanthohumol as taught by Erdelmeier et al. As evidenced by Babish et al. it was well known in the art to remove supercritical carbon dioxide from the extract in order to achieve a higher concentration of extract by simply release the pressure to volatilize the carbon dioxide. Thus, it would also have been obvious to one skilled in the

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art to separate the CO<sub>2</sub> as a solvent after extraction by releasing the pressure to volatize the CO<sub>2</sub> as taught by Babish et al.

***Response to Arguments***

Applicant's arguments filed on November 27, 2006 have been fully considered but they are not persuasive.

Regarding applicant's argument on p.10 of Reply to the Office Action of 07/26/2006 that "Kuhrt is silent with respect to the particular conditions of supercritical extraction", the argument has been considered but is moot in view of the new ground(s) of rejection (see above regarding claims 1, 2 and 8).

In response to applicant's argument on p.10 of the reply that both Babish and Erdelmeier et al recite "conventional supercritical conditions", it is noted that this is a general teaching of using supercritical extraction. Erdelmeier et al. teach it was well known in the art to carry out several extractions of hop material using supercritical carbon dioxide in order to increase content of prenylated chalcones (xanthohumol). Babish et al. teach it was well known in the art to remove supercritical carbon dioxide from the extract in order to achieve a higher concentration of extract by simply release the pressure to volatize the carbon dioxide.

Applicant's argument on p.11 of the reply that "it is clear that none of the cited references discloses or suggests a supercritical extraction of hop to obtain xanthohumol using the extreme conditions claimed therein" has been considered but is moot in view of the new ground(s) of rejection (see above regarding claims 1, 2 and 8).

**Claims 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuhrts (US 2003/0228369) in view of Pilz et al (US 4,263,253), Ohnogi et al. (US 2004/0002423).**

Kuhrts (US 2003/0228369) discloses a process of producing powders from high viscosity fluids such as xanthohumol concentrated extracts.

Kuhrts (US 2003/0228369) is silent about admixing powders into solid, pasty or liquid food, appropriate organic solvent such as ethanol, concentration of ethanol, and method of adding extract to food.

Ohnogi et al. (US 2004/0002423) disclose "food, beverage or feed for enhancing growth factor production, comprising an extract from *Humulus lupulus* (hops)" [0035].

Ohnogi et al. (US 2004/0002423) teach "an ethanol extract derived from *Humulus lupulus* ... may be contained in food or beverage" [0157]. Ohnogi et al also discloses xanthohumol derived from hops is contained in food or beverages [0151].

Conveying process is well known in the art as a method of continuous addition. As evidenced by Ohnogi et al., it is well known in the art to add ethanol based hop extracts to food and beverages. It would have been obvious to one skilled in the art to add xanthohumol-concentrated hop extract in either dry form as taught by Kuhrts or in ethanol based form as taught by Ohnogi et al. in order to produce a product that enhances growth factor and is excellent in health enhancement. It would also have been obvious to one skilled in the art to employ conveying process for continuous addition in order to optimize the process. It would have been obvious to one skilled in



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the art to determine the particular percentage of xanthohumol-concentrated hop extract in the solution by routine experimentation in order to achieve the optimal result.

### ***Response to Arguments***

Applicant's argument on p.11 of the reply regarding claims 9-13 are not deemed persuasive. In response to applicant's argument that "Ohnogi adds nothing to Kuhrts", it is noted that Ohnogi et al tech adding hop extract (particularly xanthohumol extract) to food and beverages for health enhancement ([0001], [0151]). In response to applicant's argument on p.11 of the reply that "Ohnogi adds nothing to Kuhrts, because Ohnogi disclose adding an ethanol extract derived from hops", it is noted that ethanol extract disclosed by Ohnogi et al serves as an example of extracts added to foods and beverages, and shows that ethanol may be used as an appropriate organic solvent as recited in claim 11.

### ***Conclusion***


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Stulii whose telephone number is (571) 272-3221. The examiner can normally be reached on 7:00 am-3:30 pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VS

  
**KEITH HENDRICKS**  
**PRIMARY EXAMINER**